UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,		
Plaintiff,	:	Civil Action No. 05-11805-NMG
v.	:	
RICHARD F. SELDEN,	:	
Defendant.	:	
RICHARD F. SELDEN,	:	
Plaintiff,	:	Civil Action No. 06-11807-NMG
v.	:	
UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration,	:	
Defendants.	:	

RICHARD F. SELDEN'S MEMORANDUM OF LAW IN SUPPORT OF HIS MOTION TO COMPEL FDA DEPOSITIONS

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Dated: February 19, 2007

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PRELIMINARY STATEMENT

Once again, Richard F. Selden ("Dr. Selden") finds himself in the position of having to seek this Court's assistance in the face of the federal government's continued refusal to comply with its discovery obligations, its own precedent and basic principles of fairness. As the Court knows, Dr. Selden has been fighting since October 2005 to obtain relevant discovery from the U.S. Food and Drug Administration[1] for his defense against charges of securities fraud brought by the Securities and Exchange Commission ("SEC") in S.E.C. v. Richard F. Selden, Civ. No. 05-11805-NMG (D. Mass., filed Sept. 1, 2005) (the "SEC Action"). That long and difficult history has been recounted to this Court before and will not be repeated here.[2]

Now, having finally obtained a federal court order requiring the FDA to produce documents (Protective Order, S.E.C. v. Richard F. Selden, Misc. Case No. 05-00476-RMU (D.D.C. Nov. 21, 2006) (the "D.C. Action")),[3] Dr. Selden faces the FDA's refusal to produce witnesses. Specifically, Dr. Selden requested the depositions of four FDA employees: James Kaiser, Dwaine Rieves, Marc Walton and Karen Weiss. In response, the FDA denied Dr. Selden's request with respect to three of them (Kaiser, Rieves and Weiss), and with respect to the remaining witness (Walton), limited the permissible lines of

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1 For purposes of this motion, "FDA" shall refer collectively to the United States Food and Drug Administration and Andrew C. von Eschenbach, in his official capacity as its commissioner.

2 See, e.g., Def. Richard F. Selden's Stmt. In Connection With The Sept. 28, 2006 Status Conf. (Docket No. 17), S.E.C. v. Selden, Civ. No. 05-11805-NMG (D. Mass. Sept. 20, 2006); Aff. of Justin J. Daniels In Support Of Pl.'s Mot. For Order To Show Cause And Prelim. Inj. (Docket No. 4), Richard F. Selden v. FDA, et al., Civ. No. 06-11807-NMG (D. Mass. Oct. 5, 2006); Richard F. Selden's Memo. Of Law In Support Of His Cross-Mot. To Preclude Admission Of FDA Evidence (Docket No. 20), S.E.C. v. Selden, Civ. No. 05-11805-NMG (D. Mass. Oct. 27, 2006).

3 A copy of the Protective Order is attached as "Exhibit A" to the parties' Jt. Mot. To Amend Scheduling Order (Docket No. 24), S.E.C. v. Selden, Civ. No. 05-11805-NMG (D. Mass. Nov. 21, 2006).

questioning to just two subjects. In its denial, the FDA claimed that Dr. Selden had not given a sufficient explanation of the witnesses' relevance or why this action is any different from other "third-party" securities cases involving the FDA.

The FDA's continuing antagonism toward Dr. Selden's discovery requests must be brought to an end. For sixteen months, he has fought to obtain information for his defense against the SEC, and for sixteen months the FDA has done everything in its power to block him. The SEC, by contrast, has enjoyed virtually unfettered access to the FDA during its investigation, including immediate responses to its numerous document requests as well as the provision of FDA witnesses for both "off the record" and formal testimony. In fact, Dr. Selden recently learned that the FDA and SEC are now consulting behind the scenes in advance of conferences before this Court.

The FDA's conduct is even less defensible when compared to its response to defendants' requests in S.E.C. v. Biopure Corp., et al., Civ. No. 05-11853-PBS (D. Mass., filed Sept. 14, 2005), a case involving similar claims by the SEC that a bio-pharmaceutical company misrepresented its FDA status. In Biopure, the FDA granted defendants' requests for testimony based on grounds virtually identical to those rejected by the FDA here.[4]

For all of these reasons, and as further described below, the Court should grant Dr. Selden's motion to compel the depositions of the four requested FDA employees.

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[4] See the FDA's Aug. 21, 2006 letter in Biopure (attached hereto at Tab A, and discussed infra at pp. 10-13). Perhaps the explanation for this differing treatment lies in the fact that at a March 16, 2006 scheduling conference in S.E.C. v. Biopure, the Court stated that the FDA must comply with proper discovery requests "immediately . . . not when the agency gets around to it," that it would hold the FDA "in contempt" for failing to do so, and that the SEC should help defendants obtain discovery from the FDA because otherwise the SEC's case "is going to suffer." See Mar. 16, 2006 [misdated "Mar. 31, 2006"] Tr. in S.E.C. v. Biopure, at 6-10 (attached hereto at Tab B).

BACKGROUND

This case concerns the SEC's charges of federal securities fraud arising from the FDA's review for domestic marketing approval of Replagal, Transkaryotic Therapies, Inc.'s ("TKT's") drug for the treatment of Fabry disease, a rare genetic disorder. According to the SEC, Dr. Selden, in his position as CEO of TKT, is responsible for a "series of [allegedly] materially misleading public statements by TKT about the status of the FDA application for Replagal." Complaint (Docket No. 1), S.E.C. v. Selden, Civ. No. 05-11805-NMG (D. Mass. Sept. 1, 2005) ("SEC Compl.") ¶ 1.

The SEC's case is based entirely on the FDA's review of TKT's application for Replagal, the FDA's communications with TKT in this regard and the steps both the FDA and TKT perceived as necessary for Replagal to obtain marketing approval in the United States. See, e.g., SEC Compl. ¶¶ 2-4, 12-14, 21-22, 24-26, 28-33, 35, 38-39, 41-42, 44-53, 55, 59-60, 62, 66, 70 & 74. For example, the SEC alleges that "TKT and Selden misrepresented that clinical trials for TKT's flagship drug, Replagal, were a success and made positive statements about Replagal's chances of being approved for sale in the U.S. by the [FDA]." Id. ¶ 1. The FDA is therefore a critical, if not the critical, witness. In fact, based on documents produced to date, there appear to have been at least 30 different FDA supervisors reviewing Replagal during the relevant time periods and at least 45 different FDA representatives directly communicating with TKT around the same time.

Despite the scores of FDA employees with potentially relevant testimony, Dr. Selden seeks the testimony of only four: James Kaiser, Dwaine Rieves, Marc Walton and Karen Weiss. Dr. Selden's initial request was made on March 29, 2006 pursuant to the FDA's Touhy regulations, see 21 C.F.R. § 20.1, et seq., the FDA's internal guidelines

governing requests for testimony. The request identified the four individuals and summarized the subject matters of the anticipated testimony. (A copy of Dr. Selden's March 29, 2006 submission is attached hereto at Tab C.)

The FDA responded three months later, on July 10, 2006. With respect to three of the four witnesses (Kaiser, Rieves and Weiss), the FDA denied Dr. Selden's request in its entirety on the grounds that the testimony would be duplicative of Dr. Walton's. (A copy of the FDA's letter, dated "June 30, 2006" but received on July 10, 2006, is attached hereto at Tab D.) With respect to the only witness that the FDA did permit (Walton), it limited the permissible subjects for testimony to only two: the "FDA's drug approval process" and "[Dr. Walton's] involvement in that process as it relates to [TKT's] Replagal product." Id. at 2.

Two days later, Dr. Selden requested the FDA's reconsideration of its denial. (A copy of Dr. Selden's July 12, 2006 letter is attached hereto at Tab E.) Among other things, Dr. Selden pointed out several of the ways in which the anticipated testimony from Kaiser, Rieves and Weiss would not be duplicative of Dr. Walton, and also explained why it was inappropriate for the FDA to limit the scope of Dr. Walton's testimony. Id. at 3.

Despite numerous requests by Dr. Selden's counsel seeking a prompt response from the FDA, and the agency stating it would give one, the FDA did not respond for five months. (A copy of the FDA's December 20, 2006 letter, faxed on December 21, is attached hereto at Tab F.) In its response, Carl Draper, the new Director of Compliance of the FDA's Office of Enforcement, denied the request for reconsideration in all respects.

On January 29, 2007, Dr. Selden moved to supplement his Complaint in Richard F. Selden v. FDA, et al., Civ. No. 06-11807-NMG (D. Mass., filed Oct. 5, 2006) (the

"FDA Action"), pursuant to Fed. R. Civ. P. 15(d), to address these occurrences and events and to assert additional claims for relief based thereon.[5] The FDA took no position on the motion, but indicated that it may move to dismiss the proposed Amended Complaint on the ground of the "first-to-file" rule in light of the D.C. Action.[6]

ARGUMENT

I. THE COURT'S JURISDICTION IS NOT AT ISSUE

Earlier in this case, a question arose concerning the Court's subject matter jurisdiction.[7] On October 5, 2006, Dr. Selden moved for a preliminary injunction in this Court in connection with the FDA's document production. At that time, the FDA argued that the D.C. Court had exclusive jurisdiction over the matter because it had previously ruled on the underlying subpoenas. The parties briefed the issue at that time and the Court took the matter under advisement,[8] but the question was ultimately mooted by subsequent entry of the November 21, 2006 Protective Order in the D.C. Action.

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5 See Pl.'s Mot. To Amend The Compl. (Docket No. 22), Selden v. FDA, Civ. No. 06-11807-NMG (D. Mass. Jan. 29, 2007). That motion is pending.

6 Def.'s Resp. To Pl.'s Mot. To Supplement The Compl. (Docket No. 23), Selden v. FDA, Civ. No. 06-11807-NMG (D. Mass. Feb. 12, 2007).

7 With respect to personal jurisdiction over the FDA, however, there has never been a dispute. First, the FDA waived the defense by not raising it in its response to Dr. Selden's Complaint. Fed. R. Civ. P. 12(h)(1). Second, Section 1391 of Title 28 specifically provides for jurisdiction over the United States and its agencies in "any judicial district in which . . . (2) a substantial part of the events or omissions giving rise to the claim occurred, or … (3) the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e).

8 See, e.g., Pl.'s Stmt. Concerning This Court's Jurisdiction In This Matter (Docket No. 5), Selden v. FDA, Civ. No. 06-11807-NMG (D. Mass. Oct. 5, 2006); Memo. Of Law In Support Of Defs.' Mot. To Dismiss For Lack Of Jurisdiction (Docket No. 13), Selden v. FDA, Civ. No. 06-11807-NMG (D. Mass. Oct. 20, 2006); Pl. Richard F. Selden's Memo. Of Law In Reply To The FDA's And SEC's Oppositions And In Further Support Of His Mot. For Prelim. Inj. (Docket No. 15), Selden v. FDA, Civ. No. 06-11807-NMG (D. Mass. Oct. 27, 2006).

The instant motion does not have this issue. There are no subpoenas and the matter was never before the D.C. Court. Thus, there is no competing action and no question of jurisdiction. But even if there were, Dr. Selden addressed the issue in his earlier briefing.

Nevertheless, the FDA now suggests that it may ask the Court to defer to the D.C. Court based on the "first-to-file" rule.[9] That argument is certain to fail. It is well established that the rule requires that the two actions be "identical," such that "the overlap between the two suits is nearly complete." TPM Holdings, Inc. v. Intra-Gold Indus., Inc., 91 F.3d 1, 4 (1st Cir. 1996); see also Coady v. Ashcraft & Gerel, 223 F.3d 1, 11 (1st Cir. 2000) (rule applies to "identical" actions). In this case, the issue of the FDA depositions was never before the D.C. Court. In fact, the FDA specifically argued against Dr. Selden's request for the court to address the issue. As the FDA told the D.C. Court:

> Dr. Selden now seeks to impermissibly expand the present action to encompass his demands for the testimony of four FDA scientists. Such testimony was requested by Dr. Selden pursuant to FDA's Touhy regulations in a letter dated March 29, 2006, See 21 C.F.R. § 20.1, well after the instant litigation was begun. Thus, this request is not part of the current case.[10]

The Court agreed, noting that the requests for depositions "are not at issue here." S.E.C. v. Selden, 445 F. Supp. 2d 11, 12 n.2 (D.D.C. 2006).

As this Court once noted, "there is a strong presumption in favor of a plaintiff's forum choice." Holmes Group, Inc. v. Hamilton Beach/Proctor Silex, Inc., 249 F. Supp. 2d 12, 15 (D. Mass. 2002) (Gorton, J.) (citation and internal quotations omitted).

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[9] Def.'s Resp. To Pl.'s Mot. To Supplement The Compl. (Docket No. 23), Selden v. FDA, Civ. No. 06-11807-NMG (D. Mass. Feb. 12, 2007).

[10] Jt. Status Rpt. Regarding FDA Compliance With Def.'s Subpoenas, Exh. B at B-9 (filed simultaneously with this Court on August 25, 2006, see Def. Richard F. Selden's Notice Of Filing (Docket No. 16), S.E.C. v. Selden, Civ. No. 05-11805-NMG (D. Mass. Aug. 25, 2006)) (emphasis added).

There is absolutely no reason to disturb that presumption here. The Court can, and should, entertain Dr. Selden's motion on the merits.

II. THE FDA SHOULD BE COMPELLED TO PRODUCE ITS WITNESSES FOR TESTIMONY

A. The Witnesses Are Critical To Dr. Selden's Defense In The SEC Action

In the SEC's own words, the core of its case against Dr. Selden is "the [alleged] contrast between (a) the negative messages about the Replagal application which the FDA delivered to TKT and Selden and (b) the positive messages about the Replagal application which TKT and Selden delivered to the public."[11] In addition, the SEC claims there should be heightened materiality associated with TKT's and Dr. Selden's words because of the importance of TKT's regulatory status vis-à-vis its direct competitor, Genzyme Corp. ("Genzyme"):

> Both [TKT and Genzyme] sought "orphan drug" status which, if granted, would result in a seven-year marketing exclusivity within the U.S. The existence of competing orphan drug applications was unprecedented and, because of the "winner-take-all" effect on the first applicant to receive FDA approval, any information about the FDA's attitude toward approval of Replagal would be watched closely by investors. As one analyst described the situation, "It's an amazingly high stakes poker game [TKT] is playing with [Genzyme] -- if either company has a glitch in front of the FDA panel, that company may have to wait seven years for another chance."

SEC Compl. ¶ 13. The SEC also alleges with respect to Genzyme that during one of the critical meetings, "[t]he FDA staff left open the possibility that additional clinical data from a study that had not then been completed, or surrogate marker data of the type being proposed

[11] SEC's Stmt. Of Position Concerning Mot. For Prelim. Inj. (Docket No. 9), Selden v. F.D.A., Civ. No. 06-11807-NMG (D. Mass. Oct. 19, 2006), at 5.

by Genzyme for its competing drug, could lead to approval for Replagal on the basis of a predicted clinical benefit for kidney function." Id. ¶ 33 (emphasis added).

Based on documents produced to date, there appear to have been at least 30 different FDA supervisors reviewing Replagal during the relevant time periods and at least 45 different FDA representatives directly communicating with TKT at the same time. Despite the scores of FDA employees with potentially relevant testimony, Dr. Selden seeks the testimony of only four: James Kaiser, Dwaine Rieves, Marc Walton and Karen Weiss. Those individuals were selected for specific reasons going directly to Dr. Selden's defense against the SEC's claims. The table below sets forth some of the key points from the SEC's case along with the associated relevance of the requested witnesses:

The SEC Action	Witness Relevance
1. As noted above, the core of the SEC's case concerns the nature and content of communications from the FDA relating to Replagal. Further, the SEC alleges that Dr. Selden made material misstatements concerning "conversations with the FDA." SEC Compl. ¶ 48.	James Kaiser was the FDA employee in the most frequent contact with TKT and its representatives from 1996 through mid-2000, including during the clinical development phase and the period when TKT filed its application for marketing approval. Dwaine Rieves was the FDA employee in the most frequent contact with TKT and its representatives from mid-2000 through 2003.

The SEC Action	Witness Relevance
2. Of all of the "negative messages" supposedly communicated to TKT and Dr. Selden by the FDA, perhaps the most important as far as the SEC is concerned is the alleged communication "that [TKT's] principal clinical trial was a failure and that Replagal would not receive FDA approval based on that trial." SEC Compl. ¶ 1; see also id. ¶¶ 2, 4, 13, 14-16, 17, 18-20, 21-22, 24-26.	James Kaiser was the FDA's lead clinical reviewer for Replagal from 1996 through mid-2000. Dwaine Rieves was the FDA's lead clinical reviewer for Replagal from mid-2000 through 2003.
3. As noted above, the SEC alleges that heightened materiality should be associated with TKT's and Dr. Selden's words because of TKT's competition with Genzyme.	James Kaiser was the FDA's lead clinical reviewer for Genzyme from mid-2000 through at least 2003. Marc Walton was the supervisor of the FDA's review of the applications for both Replagal and Genzyme's competing product. Karen Weiss was senior to Marc Walton and also responsible for both the TKT and Genzyme applications.
4. In its Complaint, the SEC identifies only two significant written communications to TKT from the FDA. SEC Compl. ¶ 22 (Dec. 2000 letter); ¶ 47 (Apr. 2002 letter).	Karen Weiss signed both of those letters.
5. In its Complaint, the SEC identifies only two significant conversations between the FDA and TKT. SEC Compl. ¶¶ 31-33 (Apr. 2001 meeting); ¶ 39 (May 2001 phone call).	Dwaine Rieves, Marc Walton and Karen Weiss were all at the Apr. 2001 meeting. Dwaine Rieves and Marc Walton were both on the May 2001 phone call.

The SEC Action	Witness Relevance
6. Documents produced to date indicate that there were two key FDA senior officials making policy and other high-level decisions with respect to the TKT and Genzyme applications.	Karen Weiss was one of those two key senior officials.
7. The SEC lists six FDA employees in its initial disclosures as "likely to have discoverable information relevant to the disputed facts alleged in the Complaint."	Three of the FDA employees sought by Dr. Selden -- Dwaine Rieves, Marc Walton and Karen Weiss -- are among the six employees on the SEC's disclosures.
8. During its three-year investigation, the SEC Staff interviewed and/or consulted with several FDA employees both "on" and "off" the record.	Marc Walton gave "on-the-record" testimony and was also interviewed by the SEC Staff "off the record." Unlike with Dr. Selden, the FDA imposed no additional limitations on Dr. Walton's testimony before the SEC.

The FDA is well aware of all of the above. It has read the SEC's Complaint; it has read Dr. Selden's two Touhy letters; it has read Dr. Selden's proposed Amended Complaint in the FDA Action; it has been in direct communication with the SEC throughout the course of this litigation; and it is fully aware of the prosecutorial nature of the SEC's action against Dr. Selden. Nevertheless, knowing all it knows about this case, the FDA has denied Dr. Selden's request to take the depositions of James Kaiser, Dwaine Rieves and Karen Weiss, and limited the permissible lines of questioning for Dr. Walton.

B. The FDA's Basis For Barring The Depositions Is Not Defensible

In light of the above, and particularly when compared to the FDA's decisions regarding similar deposition requests by defendants in the S.E.C. v. Biopure action (which also involved claims by the SEC that a bio-pharmaceutical company and its officers made

misrepresentations about the status of their product before the FDA), the FDA's denials in this case are not only arbitrary and capricious, but utterly incomprehensible.

First, the FDA found that Dr. Selden "offer[ed] no explanation of how the requested testimony will also promote the objectives of the [Federal Food, Drug and Cosmetic Act (FDCA)] and the FDA, as required by Section 20.1." Tab F at 3. Yet in the Biopure matter, the FDA concluded "[a]s to the objectives of the [FDCA] and the FDA, . . . that allowing FDA employees to testify about those appropriate FDA actions, to the extent that it will further the SEC's effort to prevent and deter misrepresentations about FDA pre-market review, will constitute an appropriate policy respecting the operation of FDA activities, and will help fulfill the Commissioner's responsibility to conduct public information programs relating to the responsibilities of the FDA." Tab A at 3 (emphasis added). There is no explanation for these two diametrically opposite positions from the FDA.

Second, the FDA criticized Dr. Selden for not explaining why he could not simply rely on documents rather than testimony, given that the documents were reliable. See Tab F at 4 ("You have not demonstrated, nor even argued, that these records are in any way inaccurate or incomplete.").[12] Yet in Biopure, the FDA found that testimony was needed precisely because of the existence of important written communications: "[G]iven that the SEC alleges that the defendants failed to disclose the true scope and nature of the deficiencies that FDA's July 30, 2003 complete response letter identified, it appears that a prerequisite for the case to proceed would be allowing the defendants to take the depositions of Dr. Golding, who signed that letter, and Dr. Alayash, who concurred with the letter and communicated with

[12] This argument is particularly ironic given that the FDA has spent the last year and a half trying to prevent Dr. Selden from obtaining these documents.

Biopure about FDA's premarket review." Tab A at 4 (emphasis added). Again, there is no explanation for these differences of position on the part of the FDA.

Third, the FDA stated that Dr. Selden did not sufficiently explain why Dr. Walton's testimony, standing alone, was not enough or how the differences between him and the other witnesses was "relevant." Tab F at 4-5. Not only are the differences clearly relevant, as noted in the above table (see supra pp. 8-10), but in Biopure, the FDA permitted the depositions of five different FDA employees even though each was involved in the review of the same drug. Further, because the SEC's case concerns the nature of the FDA's communications with TKT, the fact that there are differences among the FDA's key contacts is inherently relevant to Dr. Selden's defense.

Fourth, the FDA claimed that Dr. Selden "offers no basis for distinguishing the S.E.C. v. Selden action from the numerous other securities cases that have been filed or will be filed relating to FDA regulated products." Tab F at 5. But Dr. Selden stated in his letter the "special circumstances of this case": "Unlike the typical Touhy request for testimony, in this case Dr. Selden is a defendant is a civil enforcement action brought by the United States government." Tab E at 1. In the Biopure matter, the FDA appeared to acknowledge the significance of this difference: "[I]f withholding such testimony would deny the defendants a fair opportunity to defend themselves, and therefore risk having the Court dismiss the case, allowing such testimony would also be in the public interest." Tab A at 3 (emphasis added). Here, by contrast, the FDA treats Dr. Selden's case as just another "third-party litigation." Tab F at 4.

Further, in attempting to restrict Dr. Selden's access to potentially exculpatory information, the FDA's conduct also threatens Dr. Selden's rights to due process and access

to the courts. See S.E.C. v. Rivlin, Civ. No. 99-1455, 1999 WL 1455758, *3 (D.D.C. Dec. 20, 1999) (recognizing that a defendant has "full due process rights" when "the SEC, pursuant to its investigation, either files a complaint or makes a criminal reference") (citation omitted). For example, in Davis v. Lehane, 89 F. Supp. 2d 142, 155-56 (D. Mass. 2000) (Young, C.J.), the Court held that a government official's efforts to convince a relevant witness not to be interviewed by the petitioner constituted a violation of the petitioner's due process rights. As stated by the D.C. Circuit, "the paramount interest of the Government in having justice done between litigants in the Federal courts militates in favor of requiring a great effort on its part to produce any documents relevant to a fair termination of this litigation." Westinghouse Elec. Corp. v. City of Burlington, 351 F.2d 762, 767 (D.C. Cir. 1965). The FDA's actions with respect to Dr. Selden's requests for testimony are an affront to that goal.

Fifth, with respect to the limitations on the scope of Dr. Walton's testimony, the FDA takes no account of the varying allegations in the SEC's Complaint, such as the allegedly "unprecedented" nature of TKT's competition with Genzyme. SEC Compl. ¶ 13. Yet in Biopure, the FDA authorized testimony "relevant to the SEC's allegations and to the defendants' defense." Tab A at 4. Here, Dr. Selden seeks testimony concerning the SEC's allegations, including, but not limited to, Replagal, Genzyme and the FDA review process generally. Finally, the FDA's statement that it is limiting the testimony, in part, to protect against the disclosure of "confidential or proprietary information" (see Tab F at 5) is inapplicable because there is already a protective order specifically designed to permit the disclosure of confidential commercial information.

C. Dr. Selden Should Have Equal Access To Government Witnesses

The SEC's case against Dr. Selden did not begin when it filed its Complaint on September 1, 2005. It began three years earlier, in October of 2002, when the SEC commenced its investigation and started collecting information, documents and testimony on the same issues now presented in the SEC's enforcement action. During this ex parte process, the SEC sought and obtained extensive information from the FDA, including the voluntary production of documents and testimony. The FDA also provided substantive assistance to the SEC, including assistance from some of the same individuals responsible for the FDA's review of TKT's Replagal application. For example, within weeks after the start of the investigation, the FDA began allowing SEC staff members to conduct informal, "off the record" interviews of key FDA witnesses. Also, in early February 2004, in the midst of the investigation, the SEC and FDA simultaneously announced their partnership relating to securities law enforcement. The relevant announcements and press releases can be found on the FDA's website at http://www.fda.gov/bbs/topics/NEWS/2004/NEW01019.html (last visited Feb. 19, 2007).

The FDA is a most important witness in this matter and is certainly central to Dr. Selden's defense. Yet despite the unfettered access, cooperation and assistance that the FDA provided to the SEC, the FDA has tried essentially every means in its power to oppose Dr. Selden's legitimate attempt to seek his own discovery. The FDA should be required to give Dr. Selden's requests the same weight that it has given to the SEC.

CONCLUSION

For these reasons, Dr. Selden submits that the FDA should be compelled to produce the four requested FDA employees for deposition by Dr. Selden concerning the allegations in the SEC Action.

Dated: February 19, 2007
Boston, Massachusetts

Respectfully submitted,

/s/ Thomas J. Dougherty

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CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on February 19, 2007.

Dated: February 19, 2007 /s/ Justin J. Daniels
Justin J. Daniels

Tab A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

VIA FEDERAL EXPRESS

August 21, 2006

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Re: Requests for FDA testimony related to *SEC v. Biopure Corp., et al.*, Civ. No. 05-11853-PBS (D.Mass)

Dear Mr. Levine and Ms. Cormier:

This letter responds to your letters dated March 24, 2006, and March 29, 2006 to the United States Food and Drug Administration (FDA). Collectively, your letters request the testimony of six FDA employees: Dr. Lawrence Landow, Dr. Toby Silverman, Franklin Stephenson, Dr. Abdu Alayash, Dr. Basil Golding, and Dr. Jay Epstein. You both state that you seek their testimony to obtain evidence with which to defend your respective clients, Thomas Moore and Howard Richman, in *SEC v. Biopure Corp., et al.*, Civ. No. 05-11853-PBS (D.Mass) (hereinafter *SEC v. Biopure*). For the reasons set forth below, I grant your request for testimony from Drs. Landow, Silverman, Alayash, and Golding, and from Mr. Stephenson, but only for testimony relevant to defending against the SEC's claims in the lawsuit, as we describe more specifically below. I decline your request for testimony from Dr. Epstein, for the reasons set forth below.

I. Background

As you know, FDA has issued regulations that govern the testimony of FDA employees. Section 20.1 of Title 21 of the Code of Federal Regulations prohibits any FDA employee from providing testimony before any tribunal pertaining to any information acquired in the discharge of his or her official duties except with the express authorization of the Commissioner, or an employee designated to act on the Commissioner's behalf. As Director, Office of Enforcement, I have been delegated the authority by the Commissioner to review any requests made under 21 C.F.R. §20.1.

Congress has charged the FDA with the authority to enforce the Federal Food, Drug, and Cosmetic Act (FDCA) and other laws aimed at protecting the nation's health. In fulfilling this vital function, FDA regulates well more than 100,000 businesses involved in the annual manufacture, import, storage, promotion, sale, and distribution of nearly one trillion dollars worth of foods, drugs, devices, biological products, and cosmetics. FDA has limited resources and must continuously make difficult policy decisions as to how it may best allocate its limited staff and restricted budget. Were FDA to routinely grant requests for testimony in

cases involving products regulated by the agency, key agency personnel would spend an inordinate amount of time preparing for and providing such testimony, thereby substantially inhibiting FDA's ability to effectively safeguard the public health.

Section 20.1 allows the agency to allocate its limited resources in an efficient manner best designed to protect the public health. That regulation provides that the Commissioner (or his designee) may grant a request for testimony if it is determined that the testimony requested is (1) "in the public interest," and (2) "will promote the objectives of the [FDCA] and the [FDA]." 21 C.F.R. § 20.1 (c). Due to the vast number of requests that FDA receives for agency employees to participate in litigation to which FDA is not a party, it is not in the public interest for agency personnel to routinely break from their public health mission to provide testimony. Consequently, FDA retains the discretion to disapprove a request for testimony, even if that request fulfills the criteria in § 20.1. See 21 C.F.R. § 20.1(c) (stating that the request "may be granted" if § 20.1(c)'s criteria are met).

II. Your Requests for Testimony

Your March 24 and March 29 letters seek the testimony of six FDA employees for use in *SEC v. Biopure*. According to the SEC's Complaint filed September 14, 2005, in United States District Court for the District of Massachusetts, the defendants, including your two clients, "engaged in a fraudulent scheme to misrepresent and conceal from investors the truth about its applications for Food and Drug Administration ("FDA") approval of Hemopure." Complaint, ¶ 1. Specifically, the Complaint alleges that the defendants concealed from investors that FDA had placed Biopure's investigational new drug application (IND) on clinical hold. Complaint, ¶ 5. Furthermore, the Complaint alleges that the defendants concealed from investors that Biopure had received a complete response letter from the FDA, made false statements about Biopure's dealings with FDA, and failed to disclose the true scope and nature of the deficiencies in Biopure's biologics license application (BLA) for Hemopure that FDA identified in its complete response letter. Complaint, ¶ 5.

Mr. Levine, your March 24 letter states that you seek testimony from Dr. Landow, Dr. Silverman, and Mr. Stephenson because they provided sworn testimony to the SEC during the SEC's investigation and because the SEC has identified them as SEC witnesses at trial. Your supplemental letter dated April 24, 2006, states that even though the SEC did not designate Dr. Alayash as a potential trial witness, Dr. Alayash's testimony is indispensable to Mr. Moore's defense for several reasons. First, you state that the SEC's case concerns public statements and disclosures that the defendants made regarding FDA's pre-market review of Hemopure, and that many of the SEC's allegations concern FDA correspondence and communications involving Biopure's BLA for Hemopure. Second, you argue that as the FDA's scientific lead for the BLA, Dr. Alayash was an important evaluator and decisionmaker in the FDA's review of the BLA. Finally, you argue that Dr. Alayash's input was incorporated into the FDA's July 30, 2003 complete response letter, which you maintain is the "single most important document" in the SEC's case.

As to the prerequisites in section 20.1 as to when FDA may authorize testimony, namely, when the testimony requested is (1) "in the public interest," and (2) "will promote the objectives of the [FDCA] and the [FDA]," you state that the SEC and the FDA have announced a joint task force to help protect the investing public and maintain the integrity of the securities markets. You maintain that "a necessary component of both goals is the right of the accused to defend himself against the SEC's allegations, particularly in view of the FDA's policy of neutrality in matters unrelated to FDA business."

Ms. Cormier, your March 29 letter on behalf of Mr. Richman incorporates testimony requests contained in a February 1, 2006 letter from Biopure's counsel and in a March 2, 2006 letter from Thomas J. Dougherty on all the defendants' behalf. The February 1, 2006 letter lists the same four witnesses that Mr. Levine listed above, and provides no basis for a request under section 20.1. The March 2 letter lists two additional witness, Dr. Basil Golding and Dr. Jay Epstein. Although the March 2 request does limit the subject matter of the testimony sought to testimony that "concerns the allegations in a federal complaint filed on September 15, 2005, by the U.S. Securities and Exchange Commission," that letter does not explain why you need the testimony to defend your client.

IV. Discussion

I conclude that authorizing Drs. Landow, Silverman, Basil, and Alayash, and Mr. Franklin to provide you with deposition testimony on specific issues listed below that are relevant to your clients' defense in *SEC v. Biopure* would be in the public interest and will promote the objectives of the FDCA and the FDA. I conclude, for a number of reasons, that authorizing Dr. Epstein to provide you with deposition testimony would neither be in the public interest nor promote the objectives of the FDCA and FDA.

A. Basis for and Scope of the Depositions Granted

As discussed above, under section 20.1(c), FDA may grant a request for testimony from FDA employees if the Commissioner's designee determines that such testimony (1) will be in the public interest and (2) will promote the objectives of the Federal Food, Drug, and Cosmetic Act and the FDA. The SEC, in performing its mission to maintain the integrity of the securities market and to protect the investing public, filed a Complaint against the defendants alleging that they issued misleading statements to investors about FDA's pre-market review. To the extent that testimony from FDA witnesses is necessary for the SEC to prosecute its case, that testimony is clearly in the public interest. Similarly, if withholding such testimony would deny the defendants a fair opportunity to defend themselves, and therefore risk having the Court dismiss the case, allowing such testimony would also be in the public interest.

As to the objectives of the Federal Food, Drug, and Cosmetic Act (FDCA) and the FDA, the FDCA states that FDA's mission includes "taking appropriate action on the marketing of regulated products . . . ." FDCA, § 903(b)(1). Furthermore, the FDCA states that the Secretary of HHS, through FDA's Commissioner, is responsible for "establishing and implementing general policies respecting the management and operation of programs and activities of the [FDA]," *id.*, § 903(d)(2)(A), and for conducting "public information programs relating to the responsibilities of the FDA . . . ." *Id.*, § 903(d)(2)(D). The SEC's Complaint and Action against the defendants in *SEC v. Biopure* seeks remedies against the defendants for making misrepresentations to the public about actions that FDA had taken on Biopure's application to market an FDA-regulated product. I conclude that allowing FDA employees to testify about those appropriate FDA actions, to the extent that it will further the SEC's effort to prevent and deter misrepresentations about FDA pre-market review, will constitute an appropriate policy respecting the operation of FDA activities, and will help fulfill the Commissioner's responsibility to conduct public information programs relating to the responsibilities of the FDA.

Because the SEC has named Dr. Landow, Dr. Silverman and Mr. Franklin as trial witnesses, their testimony is obviously important for the SEC's case, and allowing the defendants to take their depositions also appears to be a prerequisite to allowing the case to proceed forward. In addition,

given that the SEC alleges that the defendants failed to disclose the true scope and nature of the deficiencies that FDA's July 30, 2003 complete response letter identified, it appears that a prerequisite for the case to proceed would be allowing the defendants to take the depositions of Dr. Golding, who signed that letter, and Dr. Alayash, who concurred with the letter and communicated with Biopure about FDA's premarket review.

However, my authorization is limited to testimony relevant to the SEC's allegations and to the defendants' defense. Specifically, I authorize each of those employees to testify:

1. About FDA's decision to place Biopure's IND for Hemopure on clinical hold, as memorialized in the April 25, 2003 letter from Dr. Golding to Dr. Richman;

2. About FDA's decisions to maintain the clinical hold on Biopure's IND for Hemopure, as memorialized letters from Dr. Golding to Dr. Richman dated May 30, 2003, and July 30, 2003;

3. About the July 30, 2003 complete response letter from the FDA; and

4. About Biopure's dealings and communications with FDA relating to the above-referenced decisions and letters.

I do not authorize those employees to testify about or reveal the following:

1. Biopure's trade secrets;

2. Biopure's confidential commercial information, unless prior to the depositions Biopure provides a written waiver of its privilege over confidential commercial information elicited from these employees, or Biopure and both of you and your clients obtain a protective order from the Court deeming the deposition transcripts and information disclosed during the depositions not to be disclosures to members of the public under 21 C.F.R. § 20.21, and prohibiting the persons attending the depositions and obtaining the transcripts from further disclosing them;

3. Trade secrets or confidential commercial information held by other companies, individuals, or entities;

4. Attorney-client communications between those employees and government lawyers;

5. Personal privacy information of individuals who are not parties to this lawsuit; and

6. Information on FDA's deliberations regarding decisions that have not been made yet.

My basis for excluding those categories of information is that either FDA is prohibited by law from disclosing that information, or testimony about those categories of information would not satisfy the standards set forth in 21 C.F.R. § 20.1.

Finally, I am granting the authorization above in reliance on the agreement among the defendants, which SEC attorney Ian Roffman memorialized in his April 21, 2006 letter to both of you, that defendants "collectively, will depose each witness only once and that each defendant will not have a separate opportunity to depose these witnesses." That understanding is critical to my determination that granting these deposition requests would not unduly interfere with these

witnesses' official duties or inappropriately diminish the agency's resources needed to perform its statutory functions. In that regard, my authorization is also premised on the understanding that you will accommodate the witnesses' schedules, and will conduct the depositions at locations most convenient to those witnesses, such as at their ordinary places of business in Rockville and Bethesda, Maryland.

B. Reasons for denying request for Dr. Epstein's testimony

Ms. Cormier, in addition to testimony from the five witness above, your request incorporates a request for testimony from Dr. Jay Epstein concerning "the allegations in a federal complaint filed on September 15, 2005, by the U.S. Securities and Exchange Commission . . . against the defendants in the U.S. District Court for the District of Massachusetts." The SEC did not name Dr. Epstein as a trial witness, and you provided no basis for seeking his testimony under section 20.1. Pursuant to the discretion that section 20.1 provides to the FDA Commissioner or his designee, I decline to authorize Dr. Epstein to provide you deposition testimony for the following reasons.

Dr. Epstein is currently employed as the Director, Office of Blood Research and Review (OBRR), at the Center for Biologics Evaluation and Research, U. S. Food and Drug Administration (FDA). In his capacity as Office Director, he supervises a group of approximately 150 people who are engaged in the regulation of and scientific research on blood products, such as red cells and immune globulins; diagnostic tests used to screen blood donors, such as tests for antibodies and nucleic acids of HIV; and other blood-related products, such as cell separation machines. He is also responsible for policy development in all areas of blood safety, including donor deferral criteria and product standards.

Although the Division of Hematology is within OBRR, it is just one of several divisions that report to Dr. Epstein. Dr. Epstein delegated responsibility for reviewing Biopure's Hemapure applications to Dr. Golding, the Director of the Division of Hematology. Dr. Epstein did not communicate with Biopure on the issues described above, nor did he play any active role in reviewing Biopure's applications or FDA's decisions on those applications. Consequently, Dr. Epstein is not in a position to testify about communications between Biopure and FDA or about the matters authorized above. Forcing managers like Dr. Epstein, who oversee a vast number of people, applications, and issues, to testify about every matter under their purview would prevent them from performing their daily duties, and would unduly burden the agency's resources and ability to perform its statutory responsibilities.

For those reasons, I deny your request to take Dr. Epstein's deposition.

If you have any questions, please contact Carl Turner, Esq., Office of Chief Counsel, at 301- 827-1146, or Ms. Anne Smith at 240-632-6844.

Sincerely,

David Elder
Director
Office of Enforcement

bcc:

HFC-1
HFC-200
HFC-230 (chron, r/f, Smith, Rhoads, Krawetz, Aims# 2006-2592,#2006-2862,#2006-3180,tesfile)
HFM-1
HFM-300 (JEpstein)
HFM-330 (BGolding)
HFM-345 (AAlayash)
HFM-380 (FStephenson)
HFM-392 (LLandow, TSilverman)
GCF-1 (MDruckman. CTurner, EBlumberg,AKempic)
HFA-224

Tab B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,
Plaintiff
-VS-
BIOPURE CORPORATION, et al,
Defendants

CA No. 05-11853-PBS
Pages 1 - 27

STATUS CONFERENCE
BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
March 31, 2006, 3:30 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

some dates with the SEC to get things accomplished and done and take it from there.

THE COURT: No. I want to set the date now. That's what I sort of want to do. I have no vested -- really, May was going to be pressing us all up against the wall, partly because of the FDA thing and partly because of my trial schedule. It was really because Biopure had been so absolutely insistent on it that I kept it there. And I guess that's one of the reasons this settled, so that's a good thing. I don't want this to fall off a cliff, though, the rest of it.

So let me just talk to you for a minute about the FDA thing. I, for the life of me, don't understand why you didn't just follow those regulations.

MS. FLEMING: We had, your Honor. We filed a Freedom of Information Act request before we were charged.

THE COURT: No. There's a very simple -- I think they're called Touhy?

MS. FLEMING: We have, your Honor, and we've had responses, but the responses are that it will take until 2009 to get us the documents.

THE COURT: Do this. Do the rule, follow the rule, okay, because I'm not putting off the trial unless you follow the rule. Okay, follow the rule. Then, if they do not comply in a timely way, which means by the time of my trial,

the SEC is going to have a problem, okay. But follow the rule because without that, I'm going to deny any request for a continuance. The rule has been there from the beginning of time.

Now, maybe you didn't know about it then, but you sure know about it now, and I don't understand why you haven't followed the rule. That puts the laboring oar on them to do it in a timely way by the time a federal judge has scheduled the trial.

Let me ask you this: Is there any principled reason why the FDA hasn't complied other than this regulation? I mean, is there something like national security, terrorism, something I'm not familiar with?

MR. ROFFMAN: Your Honor, it's actually all of them. There's two separate issues. One is documents, and the other is depositions. For depositions, it really is, they just haven't followed the rule. And as soon as they submit the request, the FDA will process it, and I think that they'll be able to get the depositions.

THE COURT: Immediately, immediately, I mean, because they can't -- you know, I know the federal government, okay. I used to be chief of civil in the U.S. Attorney's office a million years ago, and also -- also -- I've been a judge now for twelve years here, twenty years all together, okay? So it can't be when the agency gets around

to it. It's got to be immediately. But you have to cross the T and dot the I.

MS. FLEMING: Your Honor, we have. We have submitted the requests. We have done the alternate paths.

THE COURT: Well, when I got all that screaming and yelling back and forth, that wasn't what was said in my brief.

MS. FLEMING: I think what we did is cited it down in the footnotes, what steps we had taken as well to comply with -- not only with doing it under the rules of discovery in this court, but that we had taken steps to comply with the Touhy regulations, that we were doing this --

THE COURT: I wish somebody, instead of screaming about the Constitution, it would have been a lot quicker to have just told me you did the regulation and that they're just slow in responding, instead of the volumes of briefs that I got. I didn't see the fine print in some footnote somewhere.

All right, now, is it correct she's now followed the regulations?

MR. ROFFMAN: Your Honor, with respect to -- I don't think they have with respect to depositions, but --

THE COURT: Why? What haven't they done it?

MR. ROFFMAN: What they have to do is write a letter that explains the reason why they need testimony

addressed to the Commissioner of the FDA.

THE COURT: Would you help because your case is going to suffer?

MR. ROFFMAN: I will. And if they've done it, I've never seen it.

THE COURT: Do you have the letter that you've written?

MS. FLEMING: I don't have the letter with me, your Honor. I have the footnote which refers to the steps --

THE COURT: You know, the briefing was annoying because it was talking -- it's a very -- it puts the thing in a totally different setting when you're talking about due process clause and you don't tell me you followed the regulation. So why don't you file with me exactly what you did on the Touhy regulation, all right?

MS. FLEMING: We will do it, your Honor. We will do it.

THE COURT: So let's assume that they've done it. What is the FDA telling you about how quickly they can get a turnaround on it?

MR. ROFFMAN: Well, can I just address the documents for a second because I think that's a separate issue. The FDA really has an agencywide and, I think, legitimate concern about documents because they get subpoenas, Congressional requests, terrorism-related

requests, and they have an enormous backlog. But what we can do to try and get through that is -- and I've spoken briefly with Mr. Moore's counsel about this -- if the defendants can have what's a reasonable narrowly tailored request, there is a regulation which allows us as another federal agency to request outside of the FOIA regulations, and we will make the request for those documents.

THE COURT: This isn't FOIA. This is discovery. We're not talking FOIA; we're talking discovery. And so what T does she have to cross and I to dot to get the documents, the Touhy regulations again?

MR. ROFFMAN: Again, it's the Touhy regulations.

THE COURT: Has she done that?

MR. ROFFMAN: With the Touhy regulations, the FDA takes the position, as they're entitled to under the law, that a document subpoena gets put in the FOIA cue.

THE COURT: You know what? I'll find them in contempt. They'll subpoena the stuff to court here. That's not acceptable. Now, it has to be narrowly tailored. I'll be sympathetic if it's everything but the kitchen sink, but if there's an ongoing trial which the government is pressing forward with, they can't do that.

MR. ROFFMAN: As long as it's narrowly tailored, we can get the documents.

THE COURT: Good.

Tab C

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
ONE BEACON STREET
BOSTON, MASSACHUSETTS 02108-3194
TEL: (617) 573-4800
FAX: (617) 573-4822
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March 29, 2006

BY OVERNIGHT COURIER

Dr. Andrew C. von Eschenbach
Acting Commissioner
U.S. Food and Drug Administration
Office of the Commissioner
Parklawn Building
Mail Code: HF-1
5600 Fishers Lane
Rockville, MD 20856

Re: S.E.C. v. Richard F. Selden
Civil Action No. 05-11805-NMG (D. Mass.)

To The Commissioner:

We refer you to the Food and Drug Administration's ("FDA's") failure to make the requisite replies to the following Touhy requests:

Oct. 28, 2005 Subpoena on FDA Keeper of Records ("Touhy 1") (Tab 1)
Oct. 28, 2005 Subpoena on CBER Keeper of Records ("Touhy 2") (Tab 2)*

This request constitutes yet another attempt to obtain information from the FDA on the issues herein identified. On behalf of Richard F. Selden ("Dr. Selden"), we hereby request, pursuant to 21 C.F.R. § 20.1(c), the sworn oral testimony of the

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* The FDA opposes compliance with Touhy 1 and Touhy 2, arguing that Rule 45 of the Federal Rules of Civil Procedure does not apply to the federal government, which position is presently the subject of motion to compel proceedings before the D.C. District Court. See S.E.C. v. Richard F. Selden, No. 1:05-ms-00476-RMU (D.D.C., filed Nov. 23, 2005). Regardless of the enforceability of the subpoenas as subpoenas, however, the FDA is required by its own regulations to treat the subpoenas as "Touhy" requests to the extent they call for the production of documents. 21 C.F.R. § 20.2(a).

following FDA staff members at a mutually convenient time and at the location indicated below:

Name	Location
James Kaiser	Skadden, Arps, Slate,
Dwaine Rieves	Meagher & Flom LLP
Marc K. Walton	1440 New York Avenue, N.W.
Karen Weiss	Washington, D.C. 20005-2111

The subject matter of the testimony sought by Dr. Selden concerns the allegations in a federal complaint filed on September 1, 2005, by the U.S. Securities and Exchange Commission ("SEC") against Dr. Selden in the U.S. District Court for the District of Massachusetts, a copy of which is attached at Tab 3. The testimony shall be used as part of the defense in that action.**

In addition, in advance of the testimony, we require the production of the documents identified in the respective Schedule As of Touhy 1 and Touhy 2. As always, we remain willing to negotiate the scope of the requests, on a request-by-request basis, to try to minimize the FDA's concerns about burden and to obtain promptly those documents that are essential to Dr. Selden's defense.

The foregoing requests are made by Dr. Selden with full reservation of all of his rights relating to the subpoenas. Dr. Selden believes he is entitled to full FDA compliance with the subpoenas, particularly in the context of this case, in which the government is the plaintiff and the FDA actively cooperated with and supported the SEC in bringing the action.

** The SEC took the ex parte, sworn testimony from Marc K. Walton pursuant to requests made on or about June 25, 2003. See the June 26, 2003 letter from Lana L. Ogram, Director, Division of Compliance Policy to David P. Bergers, SEC Assistant District Administrator (referencing June 25, 2003 request), attached at Tab 4.

Please let me know if you have any questions.

Sincerely yours,

Justin J. Daniels

I verify under penalty of perjury that the foregoing is true and correct. Executed on March 29, 2006.

Justin J. Daniels

Attachments

Tab D

JUL 10 2006

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

CERTIFIED MAIL
RETURN RECEIPT

June 30, 2006

Justine J. Daniels, Esquire
Skadden, Arps, Slate, Meagher & Flom LLP
One Beacon Street
Boston, Massachusetts 02108-3194

Dear Mr. Daniels:

This is in response to your letter dated March 29, 2006, requesting testimony from the Food and Drug Administration (FDA). Your letter specifically requested authorization for the testimony of Mr. James Kaiser, Mr. Rafel "Dwaine" Rieves, Dr. Marc K. Walton and Ms. Karen Weiss in connection with a case entitled SEC v. Selden, Civ. No. 05-11805 (D. Mass. filed Sept. 1, 2005).

As you know, your request for the testimony of an FDA employee is governed by the U.S. Code of Federal Regulations (C.F.R.), Title 21 Part 20. This regulation prohibits any FDA employee from providing testimony before any tribunal pertaining to any information acquired in the discharge of his or her official duties except with the express authorization of the Commissioner of Food and Drugs or an employee designated by him to act on his behalf. As Director of the Division of Compliance Policy in the Office of Enforcement, I have been delegated the authority by the Commissioner of Food and Drugs to review any requests made under 21 C.F.R. Part 20.

Congress has charged FDA with the authority to enforce the Federal Food, Drug, and Cosmetic Act (FDCA) and other laws aimed at protecting the nation's health. In fulfilling this vital function, FDA regulates the manufacture, import, storage, promotion, sale, and distribution of nearly one trillion dollars worth of foods, drugs, devices, biological products, and cosmetics produced annually by more than 100,000 businesses worldwide. FDA has limited resources and must continuously make difficult policy decisions as to how it may best allocate its restricted staff and finite budget. Were FDA to provide testimony in all cases involving products regulated by the agency, key agency personnel would spend an inordinate amount of time preparing for and providing testimony in litigation to which the agency is not a party. This would substantially inhibit FDA's ability to effectively safeguard the public health.

Section 20.1, 21 C.F.R., provides that a request for testimony may be granted upon a determination that the testimony requested both is in the interest of the public health and in furtherance of the objectives of the FDCA and the agency. Because of FDA's limited resources and the vast number of requests the agency receives for its personnel to testify in litigation to which FDA is not a party, FDA may, in its discretion, disapprove a request for testimony even when these prerequisites have been met. In addition, FDA must deny requests that are duplicative, unlikely to elicit relevant testimony, unduly burdensome, or otherwise inappropriate. The agency must therefore carefully assess requests for testimony made pursuant to section 20.1.

After considering the merits of your requests, FDA has determined that your request to depose Dr. Marc K. Walton is in the public interest and promotes the objectives of the FDCA and the agency, and hereby authorizes him to provide certain testimony. Dr. Walton's deposition testimony shall take place at one time only, at an agreed-upon location, and shall not exceed seven (7) total hours. The deposition may be videotaped so that it may be used at trial in lieu of Dr. Walton's appearance. No information entitled to protection as a trade secret shall be revealed by Dr. Walton. See 21 U.S.C. § 331(j). Dr. Walton will testify only to facts regarding FDA's drug approval process and his involvement in that process as it relates to Trankaryotic Therapies Inc.'s Replagal product. He will not offer expert opinions on any manner and will be instructed not to answer any questions outside of the scope of the questioning authorized by this letter. You may contact Jennifer Zachary, Esq., in FDA's Office of Chief Counsel at 301-827-9572 to arrange a time and date for Dr. Walton's testimony.

In addition, pursuant to 21 C.F.R. § 20.1, I am denying your request for the testimony of Mr. James Kaiser, Mr. Rafel Rieves, and Ms. Karen Weiss because their testimony will likely be duplicative of Dr. Walton's testimony. If you have any further questions about this letter, please contact Ms. Anne Smith at 240-632-6844.

Sincerely yours,

for Carl E. Draper

Lana L. Ogram
Director
Division of Compliance Policy
Office of Enforcement

Tab E

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

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July 12, 2006

BY OVERNIGHT U.S. MAIL

Lana L. Ogram
Director, Division of Compliance Policy
c/o Anne P. Smith (HCF-230)
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: SEC v. Richard F. Selden
Civil Action No. 05-11805-NMG (D. Mass.)

Dear Ms. Ogram:

I am writing in response to your letter of June 30, 2006, which we received on July 10, 2006, regarding our requests for testimony from James Kaiser, Dwaine Rieves, Marc Walton and Karen Weiss, which we made on behalf of Dr. Richard Selden in connection with the above-captioned litigation. Respectfully, we believe that your decision not to authorize any testimony from either Kaiser, Rieves or Weiss, on the grounds that the testimony would be "duplicative," is both improper under the circumstances and factually incorrect. Similarly, we believe it is inappropriate under the circumstances to limit Dr. Walton's testimony to "facts regarding FDA's drug approval process and his involvement in that process as it relates to Transkaryotic Therapies, Inc.'s Replagal product." We respectfully request that you reconsider your position and permit the testimony as requested.

A. The Special Circumstances Of This Case

Unlike the typical Touhy request for testimony, in this case Dr. Selden is a defendant in a civil enforcement action brought by the United States government. His requests are made solely in connection with his defense in that action. The SEC has charged Dr. Selden with securities fraud relating to the public disclosures by Transkaryotic Therapies, Inc. ("TKT"), of which Dr. Selden was formerly the CEO, concerning the regulatory status of TKT's biologics license application ("BLA") for

Replagal and the relation of that status to the BLA for a similar product submitted concurrently by Genzyme Corporation. The FDA plays a critical role in Dr. Selden's defense of the SEC action. Further, the SEC has had the assistance and cooperation of the FDA. For example, the FDA has already permitted the SEC to conduct informal "off the record" interviews of Dr. Walton. Permitting private citizens a complete defense to a federal governmental enforcement action is surely in the public interest.

B. The Different Roles Of Drs. Weiss, Walton, Rieves and Kaiser

In addition to the special circumstances articulated above, it is incorrect that the other witnesses' testimony will be duplicative of Dr. Walton's testimony. Although the other witnesses, like Dr. Walton, were all involved with the review of TKT's BLA for Replagal in one way or another, that is where the similarity ends. Each of these individuals in fact played unique and distinct roles in the process, were of different levels of seniority, had different interactions with the company, and spent varying amounts of time on the BLA.

Dr. Weiss. Dr. Weiss was Dr. Walton's supervisor in connection with the clinical review of TKT's BLA for Replagal. She was at a decision-making level in regard to the application. She also had conversations with TKT representatives that were not attended by Dr. Walton or the other witnesses. Only she can competently testify as to those conversations and to her knowledge regarding the decision-making process at FDA concerning the BLA. Even Dr. Rieves indicated in written documentation that Dr. Weiss, not Dr. Walton, would be involved in deciding what statistical measures and weightings to apply in gauging the efficacy of the Replagal product. Dr. Weiss was also the signatory on certain important correspondence from the FDA to TKT and thus has personal knowledge of that correspondence.

Dr. Rieves. Dr. Rieves was the primary reviewer for the BLA for Replagal. He had extensive conversations with TKT representatives outside the presence of Dr. Walton or the other requested witnesses. Unlike Dr. Walton, we believe, Dr. Rieves personally reviewed the raw data provided by TKT during the course of the BLA process. It is also our understanding that Dr. Rieves was responsible for the first draft both of the "complete response letter" provided to TKT on January 3, 2001 as well as the FDA's August 2002 "briefing book" prepared for the FDA Advisory Committee Meeting.

Dr. Kaiser. It is our understanding that Dr. Kaiser, unlike the other witnesses, had a more direct role in connection with the design of TKT's clinical trials for Replagal as part of the IND. He also had extensive conversations with TKT outside the presence of the other witnesses.

Dr. Walton. While Dr. Walton certainly played a part in the FDA's review of TKT's BLA for Replagal, he was far from the only individual involved. In fact, he testified to the SEC on July 22, 2003 that he spent only 10% of his time on the BLA. Further, he was not the primary reviewer of the BLA.

Finally, for the reasons stated above, even if there is subject matter for which these witnesses share knowledge, that is not grounds to preclude their testimony where the individual requesting the testimony is a defendant in a federal court action brought by the federal government with the active assistance and cooperation of the FDA.

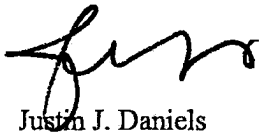
C. Restricting Dr. Walton's Testimony Is Inappropriate Under The Circumstances

You do not explain why you have determined to limit the scope of permissible questions of Dr. Walton, although we presume from the context of the letter that the reason has to do with issues of confidentiality. Again, we want to emphasize that these requests are being made in the context of a civil litigation instituted by the United States government against Dr. Selden in federal court. The FDA's objections to Dr. Walton's testimony on the grounds of confidentiality are therefore unfounded because it is common in such situations for the parties to stipulate to, and for the Court to order, the protection from disclosure of confidential information produced in the action. We would be happy to discuss the appropriate language for such a stipulation.

We ask that you please reconsider the FDA's position. We are available to discuss any of this at your convenience.

Please let me know if you have any questions.

Sincerely yours,



Justin J. Daniels

cc: Jennifer Zachary, Esq. (FDA Office of Chief Counsel)

Tab F

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

CERTIFIED MAIL
RETURN RECEIPT

December 20, 2006

Justin J. Daniels, Esquire
Skadden, Arps, Slate, Meagher & Flom LLP
One Beacon Street
Boston, Massachusetts 02108-3194

Re: **SEC v. Richard F. Selden, Civil Action No. 05-11805-NMG**
(D. Mass. filed Sept. 1, 2005)

Dear Mr. Daniels:

This letter responds to your July 12, 2006 letter seeking reconsideration of the decision by the United States Food and Drug Administration (FDA) regarding your request for the testimony of FDA employees in the above-referenced case. You have asked that FDA reconsider its decision to limit the scope of Dr. Marc Walton's testimony "to facts regarding FDA's drug approval process and his involvement in that process as it relates to Transkaryotic Therapies Inc.'s Replagal product," as well as FDA's denial of your request for the testimony of Drs. James Kaiser, Dwaine Rieves, and Karen Weiss. I understand that you have recently contacted counsel for FDA and indicated that you intend to pursue this matter further. I also understand that you have not yet deposed Dr. Walton. For the reasons set forth below, FDA declines to broaden the scope of the testimony authorized to be given by Dr. Walton and refuses to grant your requests for the testimony of the additional witnesses.

I. Background

As was explained in our June 30, 2006 letter, requests for the testimony of FDA employees are governed by Title 21, Code of Federal Regulations, Section 20.1. This regulation prohibits an FDA employee from providing testimony before any tribunal pertaining to any information acquired in the discharge of his or her official duties except with the express authorization of the Commissioner of Food and Drugs or an employee designated by him to act on his behalf. FDA enacted Section 20.1 to permit it to efficiently and fairly allocate its limited resources by funneling all requests for testimony

through a centralized decision maker who independently evaluates each request to assess both the specific disruption and cumulative impact of granting the request on FDA's ability to fulfill its mandate to regulate the nation's supply of food, drugs, and medical devices. As the Commissioner declared in the 1977 preamble to this regulation:

"The Food and Drug Administration now receives a very large number of requests for agency employees to testify in private litigation and other matters in which FDA is not a party. Were agency employees free, or required, to testify in private litigation whenever requested, the regulatory activities of the agency could be severely disrupted. The agency could not adequately function if its 6,500 employees were constantly preparing for and giving testimony in private litigation. Section [20.1] is therefore necessary for the agency to fulfill its primary regulatory responsibilities." 42 Fed. Reg. 3094, 3096 (Jan. 14, 1977).

Thus, the aim of Section 20.1 is to permit FDA to control the activities of its employees so that its principal mission --public health protection—is not compromised. Otherwise, FDA could easily be used as a repository of information and experts for litigants involved in suits that are only tangentially related to the agency's jurisdiction and mission.

Section 20.1 provides that the Commissioner (or his designee) may grant a request for testimony only upon a determination that the requested testimony (1) is "in the public interest," and (2) "will promote the objectives of the [Federal Food, Drug, and Cosmetic Act (FDCA)] and the agency." See 21 C.F.R. § 20.1(c). Due to the vast number of requests that the agency receives for its personnel to testify in litigation to which FDA is not a party, it is not in the public interest for agency personnel to routinely break from their public health mission to provide testimony. Consequently, FDA retains the discretion to disapprove a request for testimony, even where a request fulfills the criteria set forth in Section 20.1.

II. Your Request for Testimony

You have sought the deposition testimony of four FDA employees for use in SEC v. Richard F. Selden, Civil Action No. 05-11805-NMG (D. Mass. filed Sept. 1, 2005), a civil enforcement action brought by the Securities and Exchange Commission (SEC) against Dr. Selden, the former CEO of Transkaryotic Therapies Inc. (TKT), which had sought FDA approval for its Replagal product. According to the Complaint filed in this action, the SEC has alleged that:

"TKT and Selden as CEO knew but failed to disclose material negative information about Replagal's FDA application such as: (1) the pivotal trial had failed to meet its primary objective; (2) the FDA had informed TKT in January 2001 that the pivotal trial was a failed study and that its primary analysis had failed; (3) the FDA had recommended in January 2001 that TKT conduct additional clinical trials; and (4) TKT had informed the FDA, at least as early as April 2001, that it would no longer seek approval of Replagal based on a claim that the drug was effective against pain." Complaint at ¶2.

In your original request for testimony contained in your March 29, 2006 letter, you stated without elaboration that "[t]he subject matter of the testimony sought by Dr. Selden concerns allegations in the federal complaint" filed by the SEC and "shall be used as part of the defense in that action." You failed to explain how such testimony would both benefit the public interest and promote the objectives of the FDCA and the FDA, as required by Section 20.1. Nevertheless, after considering FDA's interest in preventing misrepresentations about its approval process and in assuring the truthfulness of representations to the public about the efficacy of drugs for which FDA approval has been sought, the agency authorized the testimony of Dr. Marc Walton by letter dated June 30, 2006.

In seeking reconsideration of FDA's decision to define the scope of Dr. Walton's testimony and to deny the testimony of Drs. Kaiser, Rieves, and Weiss, you argue that "[p]ermitting private citizens a complete defense to a federal government enforcement action is surely in the public interest." However, you offer no explanation of how the requested testimony will also promote the objectives of the FDCA and the FDA, as required by Section 20.1.

III. The FDA Employees

Dr. James Kaiser is a Senior Medical Officer in the Division of Pulmonary and Allergy Products in FDA's Center for Drug Evaluation and Research (CDER), where he is responsible for reviewing Investigational New Drug (IND) applications, New Drug Applications (NDAs), Biologic Licensing Applications (BLAs), and post-marketing trials and safety data for approved pulmonary and allergy drugs and biologics. In addition to his extensive review and monitoring responsibilities, Dr. Kaiser consults with other divisions within FDA needing expert guidance from the Division of Pulmonary and Allergy Products and has represented FDA at meetings with members of industry and professional associations. During the October 2000 to October 2002 timeframe specified in the Complaint, Dr. Kaiser worked on the Replagal IND submission as a Medical Officer in the Office of Therapeutics Research and Review, within FDA's Center for Biologics Evaluation and Research (CBER).

Dr. Dwaine Rieves is the Deputy Director of the Division of Medical Imaging and Hematology Products in FDA's Office of Oncology Drug Products, where he oversees the work of a group of approximately five clinical reviewers who review IND applications, NDAs, and BLAs for small molecule agents and biologics used in treating hematological conditions, such as anemias, venous thromboembolism, and platelet disorders. During the October 2000 to October 2002 timeframe specified in the Complaint, Dr. Rieves worked on the Replagal BLA as a Medical Officer within CBER's Office of Therapeutics Research and Review.

Dr. Marc Walton is a Senior Medical Policy Advisor in the Commissioner's Office of Policy, where he reviews medical data and information that may affect current or proposed FDA policies, negotiates the resolution of policy issues involving more than one component of the agency, and advises the Associate Commissioner for Policy and

other key Health and Human Services Department and FDA officials on matters relating to broad agency policy direction and development of long-range goals. During the October 2000 to October 2002 timeframe specified in the Complaint, Dr. Walton was Chief of the General Medicine Branch, Division of Clinical Trial Design and Analysis, within CBER's Office of Therapeutics Research and Review.

Dr. Karen Weiss is the Deputy Director of CDER's Office of Oncology Drug Products. This office is responsible for facilitating the rapid development, review, and approval of safe and effective new drug and biologic treatments for cancer. Dr. Weiss oversees a staff of 120 physicians, scientists, and statisticians with expertise in oncology, hematology, radiology, internal medicine, biopharmaceutics, pharmacology, toxicology, and clinical pharmacology. She must personally evaluate and make recommendations on whether to approve each new oncologic drug and biologic treatment for which FDA approval is sought. In her capacity as Deputy Director of the Office of Oncology Products, Dr. Weiss regularly attends meetings with NDA sponsors on significant issues, such as reaching agreement on protocols for critical studies that will be used to support product approval. She also attends numerous internal meetings regarding drugs under development, on adverse reactions to drug products, on agency guidelines, etc. During the October 2000 to October 2002 timeframe specified in the Complaint, Dr. Weiss was the Director of the Division of Clinical Trial Design and Analysis, within CBER's Office of Therapeutics Research and Review.

IV. Denial of Your Request for the Testimony of Drs. Kaiser, Rieves, and Weiss

FDA denied your request for the testimony of Drs. Kaiser, Rieves, and Weiss on account of its duty to "deny requests that are duplicative, unlikely to elicit relevant testimony, unduly burdensome, or otherwise inappropriate." In your letter requesting reconsideration of this denial, you state that "[e]ach of these individuals in fact played unique and distinct roles in the process, were of different levels of seniority, had different interactions with the company, and spent varying amounts of time on the BLA." However, you neglect to explain how or why any of these alleged differences are relevant in the context of your third-party litigation.

A reading of the Complaint in SEC v. Selden reveals that the only issues whereupon the testimony of FDA employees could have any possible relevance would be with respect to what information FDA communicated to representatives of TKT and when this information was communicated to them. Contemporaneous FDA records, including official correspondence, meeting minutes, and teleconference meeting minutes, carefully document each of FDA's communications with TKT. See, e.g., 21 C.F.R. §§ 10.65; 312.47. You have not demonstrated, nor even argued, that these records are in any way inaccurate or incomplete. See United States v. Chem. Found., Inc., 272 U.S. 1, 14-15 (1926) ("The presumption of regularity supports the official acts of public officers and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties."). Moreover, FDA has already authorized the testimony of Dr. Walton, who was intimately involved in FDA's review of Replagal, and authorized him to answer your questions regarding FDA's drug approval process and FDA's review

of Replagal. As noted, you have not yet scheduled his deposition. In requesting the testimony of Drs. Kaiser, Rieves, and Weiss, you do not explain what additional information you believe these three witnesses might possess that you cannot obtain from official FDA records or the testimony of Dr. Walton.

FDA makes approval decisions with respect to hundreds of regulated products each year, and, inevitably, some of these decisions are later at issue in public and private securities actions. If FDA were to routinely consent to provide testimony in litigation involving the many products it regulates, agency personnel would spend an inordinate amount of their time preparing for and testifying in securities actions, rather than accomplishing FDA's primary mission of regulating consumer products and safeguarding the public health. Your request offers no basis for distinguishing the SEC v. Selden action from the numerous other securities cases that have been filed or will be filed relating to FDA regulated products. If FDA were to grant your request, the authorization could be cited as a precedent by others seeking to depose other FDA employees on a wide variety of matters. Moreover, granting your request for the testimony of these three high-ranking FDA medical officers, in addition to the testimony of Dr. Walton that has already been authorized, would be a substantial diversion of FDA employee time and would drain seriously limited FDA resources. As such, FDA has properly denied your request as "duplicative, unlikely to elicit relevant testimony, unduly burdensome, or otherwise inappropriate," and, therefore, contrary to the public interest and the objectives of FDA.

V. Defining the Scope of Dr. Walton's Testimony

FDA has granted your request for the testimony of Dr. Walton, subject to certain limitations set forth in its June 30, 2006 letter. You seek reconsideration of FDA's decision that Dr. Walton would be authorized to "testify only to facts regarding FDA's drug approval process and his involvement in that process as it relates to Transkaryotic Therapies Inc.'s Replagal product. He will not offer expert opinions on any matter and will be instructed not to answer any questions outside of the scope of the questioning authorized by this letter." Although your request for reconsideration once again "emphasize[s] that these requests are being made in the context of a civil litigation instituted by the United States government against Dr. Selden in federal court," you do not explain how this limitation on the scope of Dr. Walton's testimony is deleterious to his defense, nor do you explain what additional areas of inquiry you seek to discuss with Dr. Walton. A reading of the Complaint in SEC v. Selden also fails to reveal any potentially relevant topics for questioning that would not be permitted under the scope of the testimony authorized to be given by Dr. Walton.

When FDA employees are authorized to provide testimony, it is standard FDA practice to define the scope of the testimony in the manner prescribed in the present case. Doing so ensures that FDA employees will not be asked to provide expert testimony, will be given a meaningful opportunity to refresh their recollection and prepare for their testimony, and will ensure that no questions are asked of the employee which may threaten to reveal the confidential or proprietary information of a third-party. See 18 U.S.C. § 1905; 21 U.S.C. § 331(j) (prohibiting the release of third-party trade secret information). Your offer to

enter into a protective order with respect to Dr. Walton's testimony is insufficient to address all of FDA's concerns that are served by clearly defining the scope of an employee's authorized testimony.

In conclusion, we find that your request to broaden the scope of the Dr. Walton's authorized testimony and to grant the testimony of Drs Kaiser, Rieves, and Weiss is not "in the public interest," and will not "promote the objectives of the [FDCA] and the agency." See 21 C.F.R. § 20.1. Therefore, FDA confirms its previous authorization pursuant to Section 20.1, that you may take the testimony of Dr. Walton subject to the limitations set forth in its June 30, 2006 letter and denies reconsideration of your request for the testimony of additional FDA employees.

As you were previously informed, FDA's Office of the General Counsel has assigned one of its attorneys, Jennifer Zachary, to assist Dr. Walton preparing his testimony. In order to make arrangements for this testimony, please contact Ms. Zachary at 301-827-9572.

Sincerely,

Carl E. Draper
Director of Compliance
Office of Enforcement